



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,042	09/29/2006	David Teh-Wei Chou	1034477-000016	8233

21839 7590 12/11/2008
BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

ZAREK, PAUL E

ART UNIT	PAPER NUMBER
----------	--------------

1617

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

12/11/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/570,042	Applicant(s) CHOU ET AL.	
	Examiner Paul Zarek	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/23/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-17 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/01/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 4161

DETAILED ACTION

Status of the Claims

1. Claims 1-7 and 10-18 are currently pending. This is the first Office Action on the merits of the claim(s).

Election/Restrictions

2. Applicant's election with traverse of Invention I, wherein compound 30 (in which R¹ is CN, R² is C1; R³ is CF₃; R⁴ is Me; R⁵ is 4-nitrophenyl; R⁶ is CF₃, A is -CH₂-CH₂-, X is CO, Y is O, W is CC1, and n is 2) is the elected species in the reply filed on 09/23/2008 is acknowledged. The traversal is on the ground(s) that the art used to break unity of invention (Phillips, et al.) was not an embodiment of a compound of the generic claim. Examiner finds the Applicant's traversal argument persuasive. The restriction requirement is vacated.

Priority

3. Applicant's claim for the benefit of a prior-filed international EP04/09378 (filed on 08/21/2004) application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 08/21/2004.

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The priority date of the instant application is 09/04/2003.

Art Unit: 4161

Claim Objections

5. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6 and 10-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (I), or composition thereof, wherein:

R¹ is -CN;

R² is a halogen;

R³ is -CF₃;

R⁴ is -CH₃;

R⁵ is -CH₃, -CH₂CH₃, isopropyl, -CH₂CH=CH₂, phenyl, 4-trifluorophenyl, 4-methylphenyl, 4-nitrophenyl, 4-methoxyphenyl, 4-ethoxyphenyl, 2,6-difluorophenyl, 2-fluorophenyl, 4-chlorophenyl, 1-methylene-2-fluorophenyl, 1-methylene-4-chlorophenyl, or 1-methylene-4-methylphenyl;

R⁶ is -CF₃,

A is -CH₂CH₂-;

W is CCl;

X is C=O or SO₂; and

Y is a covalent bond, -O-, or -NH-,

and a method of making and using said compounds and compositions, does not reasonably provide enablement for all other compounds encompassed by the claims. The specification does

Art Unit: 4161

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

8. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07, set forth eight factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” (MPEP § 2164.01(a))

a. *The breadth of the claim:* The instant claims are drawn to an exceedingly vast and diverse range of compounds. R¹ ranges from the discrete cyano group to C(=NZ)S(O)r-Q in which Z can be a range of alkyl, haloalkyl, alkenyl, alkynyl, or acyl chains possibly capped with an optionally substituted phenyl ring, and Q can be another alkyl chain possibly capped with an optionally substituted phenyl ring. R⁴ and R⁵ can be linear (C₂-C₆) or cyclic (C₃-C₇), optionally substituted alkyl, alkenyl, or alkynyl groups in which any heterocycle can contain 1, 2, or 3 heteroatoms selected from the group consisting of N, O, and S. The possible number of encompassed compounds is staggering and any one compound would not be necessarily an obvious variant of another compound selected from the same possible substituents;

b. *Nature of the invention:* The nature of the invention is a 5-oxyalkylamino-1-arylpyrazole derivative which can be used to control or kill pests on animals or surfaces;

c. *The state of the prior art:* Kando, et al. (US Patent No. 6,316,477, 2001, provided in IDS), Phillips, et al. (European Patent No. 0 500 209, 1997, provided in IDS), Jensen-Korte, et al. (US Patent No. 4,971,989, 1990, provided in IDS), Manning, et al. (International Application No. WO98/28279, 1998, provided in IDS, and Wu and Pilato

Art Unit: 4161

(US Patent No. 5,691,333, 1997, provided in IDS) teach pesticidal compositions comprising 1-arylpyrazole derivatives. Each of these references teach embodiments of the 1-arylpyrazole derivative wherein there is a -Cl or halogen at the 2 and 6 positions of the phenyl ring, and a -CF₃ at the 4 position. Each teach numerous compounds wherein a -S(O)_n- is at the 4 position of the pyrazole ring, and a -CF₃ or -CH₃, or -CH₂CH₃ attached to the -S(O)_n-. The prior art also teaches a -CN, halogen, -C(=NY)X or -C(=S)-NR at the 3 position of the pyrazole ring. The prior art further teach various substituents at the 5 position of the pyrazole ring. Such substituents are represented by Kando, et al., wherein the disclosed substituents include -NH₂, -NHCH₃, -NHCH₂CH₃, -N=CHCH₃, -NHAc, and -N(CH₂Ph)₂, among others. The pesticidal activity of the compounds taught by the prior art is disclosed in the examples. Kando, et al., demonstrate the wide variability in substituents in at the 5 position of the pyrazole ring while maintaining its activity;

d. *Level of one of ordinary skill in the art:* The skill level of an ordinarily skilled artisan would be high;

e. *Level of predictability in the art:* Collectively, Kando, et al., Phillips, et al., Jensen-Korte, et al., Manning, et al., and Wu and Pilato teach that the genus of 1-arylpyrazole derivatives is effective pesticidal compounds;

f. *Amount of direction provided by the inventor:* Applicant discloses that 1-arylpyrazole compounds are useful for the control of pests. Applicant also discloses 103 specific compounds which vary at the X, Y, and R⁵ subgroups (Table I). No compounds containing subgroups other than those described above are disclosed;

Art Unit: 4161

- g. *Existence of working examples:* Applicant demonstrates that compound nos. 6, 30, 39, 51, 54, 57, 63, 69, 72, 84, 90, and 93 demonstrated pesticidal activity against *Ctenocephalides felis*. Applicant also discloses 13 compositions comprising an “active ingredient,” which is presumably one of the compounds listed in Table I; and,
- h. *Quantity or experimentation needed to make or use the invention based on the content of the disclosure:* Applicant has made and tested only a very small subset of the possible compounds encompassed by the rejected claims. The instant specification does not provide sufficient guidance to enable one of ordinary skill in the art at the time the invention was made to make all of the huge number of compounds claimed. “Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. . . . [M]ost syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence” (Dorwald, *Side Reactions in Organic Synthesis*, 2005).

Moreover, Applicant has not provided any data suggesting that any molecule other than the small, disclosed subset of compounds would be effective pesticidal compounds. The possible embodiments claimed are not necessarily obvious variants of each other. “A patent is not a hunting license. It is not a reward for search but compensation for its successful conclusion and patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that

Art Unit: 4161

may or may not be workable." (*Genentech Inc v Nova Nordisk* 42 USPQ 2d 1001). One of ordinary skill could not reasonably determine whether the claimed compounds would be effective pesticides. The instant specification does not enable one of ordinary skill in the art to make and use the invention commensurate with the scope of the rejected claims. Undue and unpredictable experimentation would be required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 10, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kando, et al. (US Patent No. 6,316,477, 2001, provided in IDS) in view of Phillips, et al. (European Patent No. 0 500 209, 1997, provided in IDS), Jensen-Korte, et al. (US Patent No. 4,971,989, 1990, provided in IDS), Manning, et al. (International Application WO98/28279,

Art Unit: 4161

1998, provided in IDS), Wu and Pilato (US Patent 5,691,333, 1997, provided in IDS), and King (Medicinal Chemistry: Principles and Practice, 1994).

12. Claims 10 and 11 of the instant application are drawn to a method of controlling pests at a locus comprising application to said locus an effective amount of the compound formula (I) (Claim 10) or a composition comprising compound of formula (I) (Claim 11). Claims 13 and 14 are drawn to a method of controlling pests in or on an animal comprising the administration of a compound of formula (I) (Claim 13) or a veterinary medicament (i.e. composition) of the compound of formula (I) (Claim 14). The scope of compounds or compositions of formula (I) are limited to those in which R^1 is CN, R^2 is Cl, R^3 is CF_3 , R^4 is Me, R^6 is CF_3 , A is $-CH_2CH_2-$, and W is CCl.

13. Kando, et al., Phillips, et al., Jensen-Korte, et al., Manning, et al., and Wu and Pilato teach a method of treating surfaces, plants, and/or animals with 1-arylpyrazole derivatives to control pests (Kando, et al., abstract; Phillips, et al., pg 1, lines 5-7; Jensen-Korte, et al., Examples A-K and Claim 6; Manning, et al., pg 21, lines 4-35; and Wu and Pilato, col 20, line 20 to col 21 line30). Each of these references teach embodiments of the 1-arylpyrazole derivative wherein there is a -Cl or halogen at the 2 and 6 positions of the phenyl ring, and a - CF_3 at the 4 position. Each teach numerous compounds wherein a $-S(O)_n-$ is at the 4 position of the pyrazole ring, and a $-CF_3$ or $-CH_3$, or $-CH_2CH_3$ attached to the $-S(O)_n-$. The prior art also teaches a $-CN$, halogen, $-C(=NY)X$ or $-C(=S)-NR$ at the 3 position of the pyrazole ring. The prior art further teach various substituents at the 5 position of the pyrazole ring. Such substituents are represented by Kando, et al., wherein the disclosed substituents include $-NH_2$, $-NHCH_3$, $-NHCH_2CH_3$, $-N=CHCH_3$, $-NHAc$, and $-N(CH_2Ph)_2$, among others. The pesticidal

Art Unit: 4161

activities of the compounds taught by the prior art are disclosed in the examples. The prior art does not disclose a specific embodiment of the claimed compounds. The fundamental difference between the prior art and the claimed compounds is that the $-C(C=O)OR$ residue at the 5 position of the pyrazole ring is replaced with an $-OC(=O)OR$.

14. One of ordinary skill in the art would reasonably expect that the consequent compounds would maintain their pesticidal faculties. Kando, et al., demonstrate the wide variability in substituents in at the 5 position of the pyrazole ring while maintaining its activity. Moreover, King teaches that $-O-$ and $-CH_2-$ are bioisosteres (pg 208, Table 1), so one of ordinary skill in the art would not expect that changing a methylene to ether would affect the pesticidal ability of the resultant compound. Manning, et al., also teach 1-arylpyrazol compositions as veterinary medicaments (pg 23, line 28 to pg 24, line 10). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the compounds and compositions of formula (I) (which are enabled by the instant specification) for the treatment of loci (i.e. plants) and animals to control pests, given the close similarity of the claimed compounds and compositions to those of the prior art, as taught by Kando, et al., Phillips, et al., Jensen-Korte, et al., Manning, et al., and Wu and Pilato.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

Art Unit: 4161

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625